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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,744	03/15/2004	Hideo Nishibayashi	119099	9227
25944	7590	03/23/2005	EXAMINER	
OLIFF & BERRIDGE, PLC			MALLARI, PATRICIA C	
P.O. BOX 19928			ART UNIT	
ALEXANDRIA, VA 22320			PAPER NUMBER	

3736

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,744	<b>Applicant(s)</b> NISHIBAYASHI, HIDEO	
	<b>Examiner</b> Patricia C. Mallari	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/28/04</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Objections***

Claim 1 is objected to because of the following informalities:

On lines 2-4 of claim 1, "which is inflatable to press an arterial vessel of a body portion of a living subject and stop flow of blood in the arterial vessel which the inflatable cuff is adapted to be wound around the body portion" should be replaced with "adapted to be wound around a body portion of a living subject and inflatable to press an arterial vessel of the body portion and to stop flow of blood in the arterial vessel".

. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites, "a fluid-filled bag which is located between the second inflatable bag and the body portion" on the last two lines of the claim. In this case, the body portion is non-statutory subject matter which cannot be claimed positively. The applicants should amend the cited lines to read "a fluid-filled bag which is adapted to be located between the second inflatable bag and the body portion" in order to overcome this rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,572,205 to Sjönell in view of US Patent No. 6,336,901 to Itonaga et al. Sjönell discloses an inflatable cuff for blood pressure measurement comprising a first inflatable bag 5, a second inflatable bag 4, and a third bag 3 (figs. 1 and 4; col. 2, lines 15-20 of Sjönell). The first bag 1 is inflatable to press and stop blood flow within an arterial vessel in the body portion around which the cuff is wound (col. 2, lines 1-11; col. 2, line 66-col. 3, line 3 of Sjönell). The second bag 4 is supported by the cuff such that the second bag 4 is located inside a downstream-side portion of the first bag 5 as seen in the direction in which the blood flows in the arterial vessel, and which has a dimension as measured in said direction that is smaller than a dimension of the first inflatable bag 5 as measured in said direction (figs. 1 and 4; col. 2, lines 21-29 of Sjönell). The second bag 4 is also capable of being used for sensing a pulse wave propagating along the arterial vessel (col. 2, lines 18-20 of Sjönell). The third bag 3 may be located between the second inflatable bag 4 and the body portion during use (figs. 1 & 4 of Sjönell). Sjönell teaches the third bag being filled with air (col. 2, lines 18-20 of Sjönell), rather than incompressible fluid.

However, Itonaga discloses a blood pressure cuff comprising inflatable bags wherein either air or water, water being an incompressible fluid, may be used to inflate the bags (col. 9, lines 30-37 of Itonaga). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use water in place of air for inflating

any of the bags of Sjönell, since Itonaga teaches that air and water are functionally equivalent for inflating a blood pressure cuff.

The applicants should note that the language “located between the second inflatable bag and the body portion” on the last two lines of claim 1 depend largely upon use of the apparatus and therefore constitute “intended use” language, which cannot be relied upon to overcome the prior art references of Sjönell in view of Itonaga, since combined references disclose all of the claimed limitations and their recited relationships. See *Ex parte Masham* 2 USPQ 2<sup>nd</sup> 1647. The cuff of Sjönell and Itonaga may certainly be used such that the third bag 3 (figs. 1 & 4 of Sjönell) is placed on the body portion during blood pressure measurement.

Regarding claims 2 and 8, the incompressible fluid is a liquid, wherein water is a liquid.

Regarding claims 4 and 5, the third (fluid-filled) bag 3 has a size and location such that it may fill a space formed between the second bag 4 and the body portion during use (figs. 1 & 4 of Sjönell).

Regarding claims 7 and 8, the third (fluid-filled) bag 3 has a size and is located such that the second bag 4 and the third bag 3 are overlapped during use (figs. 1 & 4 of Sjönell).

Claims 3, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sjönell in view of Itonaga, as applied to claims 1, 2, 4, 5, 7, and 8 above. Sjönell, as modified, discloses the third (fluid-filled bag) 3 as being filled with water, rather than with an incompressible gel. However, the applicant has not disclosed that using an

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incompressible gel over an incompressible liquid solves any stated problem or is for any particular purpose. Moreover, it appears that the cuff would perform equally well with either an incompressible liquid or an incompressible gel. Accordingly, the use of an incompressible gel is deemed to be a design consideration that fails to patentably distinguish over the prior art of Sjönell, as modified by Itonaga.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,694,821 to Yamakoshi et al.

US Patent No. 6,527,727 to Itonaga et al.

US Patent No. 3,752,148 to Schmalzbach

US Patent No. 3,527,204 to Lem

US Patent No. 1,043,521 to Hoobler.

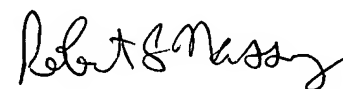
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia Mallari  
Patent Examiner  
Art Unit 3736

  
ROBERT S. MASSY  
PATENT EXAMINER